IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

CHRISTOPHER TYLER LOFTON, Individually and on behalf of the ESTATE of CHRISTOPHER M. LOFTON, et al.,	§	
Plaintiffs,	§	
v.	§	Civil Action No. **3:05-CV-1531-L**
MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS, a Division of MCNEIL-PPC, INC., and JOHNSON & JOHNSON,	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

Before the court are: (1) Defendants' Motion for Summary Judgment, filed May 2, 2008; (2) Defendants' Objections to Plaintiffs' Summary Judgment Evidence, filed June 13, 2008; and (3) Defendants' Objections to Magistrate Judge's Order, filed August 4, 2009. After carefully considering the motion, objections, record, and applicable law, the court **overrules** Defendants' Objections to Magistrate Judge's Order; **overrules as moot** Defendants' Objections to Plaintiffs' Summary Judgment Evidence; and **grants in part** and **denies in part** Defendants' Motion for Summary Judgment.

I. Background and Procedural History

Plaintiffs Christopher Tyler Lofton, individually and on behalf of the estate of Christopher M. Lofton, and Sandy Lynn Lofton, as next friend for Tegan Lofton and Lauren Lofton, on their behalf and on behalf of the estate of Christopher M. Lofton (collectively, "Plaintiffs") filed their Original Petition in the 193rd Judicial District Court, Dallas County, Texas, on July 1, 2005.

Plaintiffs brought claims of defective design, marketing defect, breach of express warranty, breach of implied warranty, negligence, and violation of the Texas Deceptive Trade Practices Act as a wrongful death action and as a survival action. Plaintiffs assert claims against Defendants McNeil Consumer & Specialty Pharmaceuticals ("McNeil") and Johnson & Johnson ("J&J") (collectively, "Defendants"). Defendants removed the action to this court on August 2, 2005. Plaintiffs twice amended their pleadings in this court, and the live pleading is their Second Amended Original Complaint ("Complaint"), filed February 27, 2006.

Plaintiffs' claims arise out of the death of Christopher M. Lofton ("Decedent"). They contend that Decedent began taking Motrin for musculoskeletal pain on May 20, 2000, and developed a rash on May 25, 2000. He was diagnosed with a viral rash in the emergency department on May 24 and 25, 2000, then visited his primary care physician, was treated with steroids, and referred for a dermatology consult on May 26, 2000. On May 27, 2000, Decedent went to the emergency department at Medical Center of Plano and was diagnosed with Stevens-Johnson Syndrome ("SJS") and toxic epidermal necrolysis ("TEN") secondary to ibuprofen. On May 28, 2000, he was transferred to the Parkland Burn unit. Decedent subsequently developed septicemia and multi-organ system failure, and he died on June 3, 2000.

After the motion for summary judgment was filed by Defendants, the parties jointly moved to abate these proceedings pending the decision by the Supreme Court in *Wyeth v. Levine*, 128 S. Ct. 1118 (2008). Before the court ruled on the motion to abate, the magistrate judge ruled on a motion to exclude or limit Plaintiffs' expert testimony on July 25, 2008. On July 30, 2008, the court administratively closed the case until the Court decided *Wyeth*.

The Supreme Court reached its decision in *Wyeth* on March 4, 2009. 555 U.S. ___, 129 S. Ct. 1187 (2009) (hereinafter, "*Wyeth*"). The parties subsequently moved to reopen the case, and the court reopened the case on July 30, 2009. Defendants thereafter filed objections to the magistrate judge's July 25, 2008 order. The court now considers the motion for summary judgment and the objections to the magistrate judge's order.

II. Objections to the Magistrate Judge's July 25, 2008 Order

A. Legal Standard

A district court may modify or set aside a magistrate judge's ruling regarding nondispositive pretrial motions only if the ruling is "clearly erroneous or contrary to law." *See* Fed. R. Civ. P. 72(a); *see also* 28 U.S.C. § 636(b)(1)(A) ("A judge of the court may reconsider any [nondispositive] pretrial matter . . . where it has been shown that the magistrate's order is clearly erroneous or contrary to law."); *Castillo v. Frank*, 70 F.3d 382, 385 (5th Cir. 1995).

B. The Magistrate Judge's July 25, 2008 Order

On July 25, 2008, the magistrate judge granted in part and denied in part Defendants' Motion to Exclude or Limit Plaintiffs' Expert Testimony. Defendants moved to exclude or limit the testimony of six of the seven expert witnesses identified by Plaintiffs to testify at trial. Defendants challenged many aspects of the six experts' testimony.

Defendants first challenged the general causation opinions of all six of the challenged experts. The magistrate judge rejected their argument that the must court apply *Merrell Dow Pharmaceuticals, Inc. v. Havner*, 953 S.W.2d 706 (Tex. 1997), because that decision considered the sufficiency of evidence to support a jury finding, not the admissibility of expert evidence under federal law. The magistrate judge next rejected Defendants' argument that Plaintiffs' experts'

opinions regarding epidemiological evidence should be rejected because these arguments go to the weight of the evidence but not its admissibility. The magistrate judge also rejected Defendants' argument regarding negation of a prior study by a more recent study, finding that this also goes to the weight of the evidence but not its admissibility.

Second, Defendants moved to exclude or limit Plaintiffs' expert testimony regarding Dr. Tackett's defective design theory. The magistrate judge determined that this evidence is admissible and Defendants' objections go to the weight, not the admissibility, of such evidence.

Third, Defendants asked the court to exclude or limit certain personal opinions expressed by Drs. Tackett, Nelson, and Salisbury. The magistrate judge agreed with Defendants and found that the personal opinion testimony proffered by these experts is inadmissible.

Fourth, Defendants argued that Plaintiffs' experts are not qualified to offer testimony regarding general causation, specific causation, and the labeling requirements of the Food and Drug Administration ("FDA"). The magistrate judge rejected these challenges, finding that Defendants' arguments go to the weight, not the admissibility, of the expert testimony.

Next, the magistrate judge considered Defendants' argument that Plaintiffs provided inadequate expert disclosures. After weighing the factors to determine if failure to disclose was harmless error as set forth in *Texas A&M Research Fund v. Magna Transportation, Inc.*, 338 F.3d 394, 402 (5th Cir. 2003), the magistrate judge determined that any violation of Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure was harmless and that the court would not limit Plaintiffs' expert testimony on this basis.

Finally, the magistrate judge considered Defendants' objection to Plaintiffs' expert testimony on the grounds that such testimony is cumulative. The magistrate judge determined that this determination is best made at trial after the parties have called experts to testify.

C. Analysis

Defendants have filed objections to the magistrate judge's July 25, 2008 order, and ask the court to overrule that order and exclude Plaintiffs' expert testimony on general causation and the defective design theory. They contend that the magistrate judge misinterpreted and misapplied the law regarding the interpretation of Rule 702 of the Federal Rules of Evidence in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and the application of *Havner* to Rule 702's relevancy requirement. Plaintiffs contend that the magistrate judge's rulings were correct and ask the court to overrule Defendants' objections.

1. General Causation

a. Relevancy

Defendants first argue that the magistrate judge's order misapplied the relevancy requirement of Rule 702 of the Federal Rules of Evidence. They contend that the court applied the relevancy standards of Rule 401 of the Federal Rules of Evidence, rather than the requirements under Rule 702.

Rule 702 provides:

> If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

The Court in *Daubert*, construing Rule 702, stated that "the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." 509 U.S. at 589. In considering the requirements of relevance and reliability, the Court noted:

> [T]he requirement that an expert's testimony pertain to scientific knowledge establishes a standard of evidentiary reliability. . . . Rule 702 further requires that the evidence or testimony assist the trier of fact to understand the evidence or to determine a fact in issue. This condition goes primarily to relevance. Expert testimony which does not relate to any issue in the case is not relevant, and, ergo, non-helpful.

Id. at 590-91 (internal citations and quotations omitted).

The magistrate judge set forth the legal standard for relevance as follows:

> In evaluating the admissibility of expert testimony, the key factors are relevance and reliability. *Daubert*, 509 U.S. at 589 (under Rule 702, expert testimony must be "not only relevant, but reliable"). The relevancy question ensures that the expert testimony will actually "assist the trier of fact to understand the evidence or to determine a fact in issue." *Id*. Federal Rule of Evidence 401 defines relevant evidence as that which has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence. Fed. R. Evid. 401. "Expert testimony which does not relate to any issue on the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. 590.

Order (July 25, 2008) 3. The court determines that although the magistrate judge cited Rule 401 for the definition of relevant evidence, the legal standard she applied, which relied upon *Daubert* and Rule 702, was the correct standard. The magistrate judge is not incorrect. In *Daubert*, the Supreme Court did not alter the definition of relevance. It merely explained and clarified the interplay between Rules 702 and 401 with respect to the use of expert testimony. Accordingly, the court finds that the magistrate judge applied the correct legal standard to determine relevancy.

b. *Havner*

The court next considers Defendants' argument that *Havner* controls the court's determination of relevancy in the context of the admissibility of expert testimony in a medical case such as this. In *Havner*, the Texas Supreme Court considered whether there was legally sufficient evidence that the drug Bendectin caused plaintiff to be born with a birth defect. 953 S.W.2d at 708. That court framed the issue as "whether the [plaintiffs'] evidence is scientifically reliable and thus some evidence to support the judgment in their favor." *Id*. at 711. The *Havner* court held that to establish some evidence of general causation, epidemiological studies must meet three standards. First, the study must show "more than a doubling of the risk" due to exposure. *Id*. at 718. Second, the study must have a confidence interval that does not include 1.0. *Id*. at 723. Third, the study must have a confidence level of at least 95 percent. *Id*. at 724.

The United States Court of Appeals for the Fifth Circuit has considered the *Havner* decision, but only in the context of determining the legal sufficiency of evidence supporting a jury verdict. In that case, although the parties appealed both the sufficiency of the evidence and the court's expert admissibility rulings, the initial panel hearing the case applied *Havner* only to its discussion of the sufficiency of the evidence to support the jury's finding. *Bartley v. Euclid, Inc.*, 158 F.3d 272 (5th Cir. 1998), *vacated*, 169 F.3d 215 (5th Cir. 1999) ("*Bartley I*"). When that case was heard *en banc*, the court did not address the applicability of *Havner* to the admissibility determination, instead focusing on the *Daubert* criteria. *Barley v. Euclid, Inc.*, 180 F.3d 175, 179 (5th Cir. 1999) ("*Bartley II*").

District courts in this circuit have reached different results in determining whether *Havner* applies to a federal court's ruling on the admissibility of expert testimony. At least one court in this

district rejected the application of *Havner* to the determination of whether expert testimony is admissible. In *Taylor v. Bristol-Myers Squibb Co.*, 2004 WL 2058796 (N.D. Tex. 2004) (Cummings, J.), the court distinguished between the legal sufficiency of evidence to prove a claim and the legal standard for admissibility of expert evidence:

> This Court is of the opinion that *Havner* does not clearly establish substantive state law that would control the admissibility of expert testimony or scientific evidence in a federal court sitting in diversity. The issue of *Havner* was not the admissibility of evidence but rather the legal sufficiency of the evidence offered to establish causation, and the holding of the case addressed only that legal sufficiency issue.

Id. at *1 (citation and footnote omitted).

Another district court considering the same issue has held that the *Havner* standards should apply in determining the admissibility of expert evidence:

> If evidence is admissible under federal procedural law but fails to constitute "some evidence" under Texas substantive law, the Plaintiffs' victory on the admissibility question would be a hollow one, as the evidence would be deemed insufficient as a matter of law to survive summary judgment. Moreover, whether expert testimony will assist the trier of fact is governed in part by whether the testimony is relevant to the plaintiff's burden of proof under the substantive law, and testimony that will not assist the trier of fact by advancing an element of the plaintiff's case should be excluded.

Cano v. Everest Minerals Corp., 362 F. Supp. 2d 814, 821-22 (W.D. Tex. 2005) (Rodriguez, J.) (citation omitted). That court concluded that "*Havner* controls the issue of what evidence is required to establish causation in a toxic tort case and therefore what evidence is relevant." *Id*. at 822; *see also Burton v. Wyeth-Ayerst Labs. Div. of American Home Prods. Corp.*, 513 F. Supp. 2d 719, 730 n.12 (N.D. Tex. 2007) (Fish, J.) (holding in dicta that "*Havner*'s standards are substantive, not procedural requirements.") (citation omitted).

Other courts, including the Fifth Circuit, have applied *Havner* to determine the legal sufficiency of the evidence supporting causation but have not reached the question of whether its standards apply in the context of a *Daubert* challenge. *Bartley I*, 158 F.3d at 272-73; *Wells v. SmithKline Beecham Corp.*, 2009 WL 564303, *2 n.4 (W.D. Tex. Feb. 18, 2009) (Yeakel, J.); *Cotroneo v. Shaw Env't & Infrastructure, Inc.*, 2007 WL 3145791, *4 (S.D. Tex. 2007) (Smith, Mag. J.). The only cases from this circuit cited by the magistrate judge and the parties regarding its applicability to a *Daubert* challenge are *Taylor* and *Cano*, and the court has not identified any other cases that are directly on point.

Regardless of the court's decision regarding the applicability of *Havner* in this context, the court will necessarily have to consider Plaintiffs' expert reports in light of *Havner* when determining the summary judgment motion. The court understands the practical decision of the court in *Cano* that evidence that may be admissible but that fails to be legally sufficient to prove general causation should be excluded. This decision, however, conflates the standards under *Daubert* and the ultimate question of whether there is legally sufficient evidence of causation. The court determines that the magistrate judge is correct and will follow *Taylor*; it finds that *Havner* does not control a federal court's determination of admissibility pursuant to Rule 702 and *Daubert*. The court notes, however, that even if this decision is incorrect, in the context of this case, Defendants' objection would be moot because in ruling on the motion for summary judgment the court will consider the sufficiency of the epidemiological studies under the standards set forth in *Havner*.

With respect to Defendants' remaining objections to the magistrate judge's order, the court determines that these objections go to the weight, not the admissibility, of the evidence. The court finds that cross-examination and careful instruction of the jury will cure Defendants' other concerns

about Plaintiffs' experts' testimony. *See Daubert*, 509 U.S. at 596. Accordingly, the court **overrules** Defendants' objections relating to the magistrate judge's decision regarding general causation.

2. Defective Design

Defendants also object because they contend that the magistrate judge erred in allowing the admission of Dr. Tackett's defective design theory. Defendants contend that his theory is untested and unpublished and therefore fails the *Daubert* reliability requirement.

Dr. Tackett opined that pure S+ ibuprofen is less likely to cause SJS or TEN than the specific mixture of R- and S+ ibuprofen in Motrin. The magistrate judge found that his opinion need not be published to be admissible and that Defendants' concerns go to the weight, not the admissibility, of the evidence.

The court agrees with the magistrate judge. Although Dr. Tackett's opinion has not been published, rather than excluding it, the court determines that better practice will be to allow him to be cross-examined and to allow Defendants to present other evidence regarding his conclusions. Accordingly, the court **overrules** Defendants' objections to the magistrate judge's order regarding the defective design theory and determines that the magistrate judge's findings and conclusions are not clearly erroneous or contrary to law.

III. Motion for Summary Judgment

A. Legal Standard

Summary judgment shall be rendered when the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter

of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-25 (1986); *Ragas v. Tennessee Gas Pipeline Co.*, 136 F.3d 455, 458 (5th Cir. 1998). A dispute regarding a material fact is "genuine" if the evidence is such that a reasonable jury could return a verdict in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). When ruling on a motion for summary judgment, the court is required to view all facts and inferences in the light most favorable to the nonmoving party and resolve all disputed facts in favor of the nonmoving party. *Boudreaux v. Swift Transp. Co., Inc.*, 402 F.3d 536, 540 (5th Cir. 2005). Further, a court "may not make credibility determinations or weigh the evidence" in ruling on motion for summary judgment. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000); *Anderson*, 477 U.S. at 254-55.

Once the moving party has made an initial showing that there is no evidence to support the nonmoving party's case, the party opposing the motion must come forward with competent summary judgment evidence of the existence of a genuine fact issue. *Matsushita Elec. Indus. Co. v. Zenith Radio*, 475 U.S. 574, 586 (1986). Mere conclusory allegations are not competent summary judgment evidence, and thus are insufficient to defeat a motion for summary judgment. *Eason v. Thaler*, 73 F.3d 1322, 1325 (5th Cir. 1996). Unsubstantiated assertions, improbable inferences, and unsupported speculation are not competent summary judgment evidence. *See Forsyth v. Barr*, 19 F.3d 1527, 1533 (5th Cir.), *cert. denied*, 513 U.S. 871 (1994). The party opposing summary judgment is required to identify specific evidence in the record and to articulate the precise manner in which that evidence supports his claim. *Ragas*, 136 F.3d at 458. Rule 56 does not impose a duty on the court to "sift through the record in search of evidence" to support the nonmovant's opposition to the motion for summary judgment. *Id.*; *see also Skotak v. Tenneco Resins, Inc.*, 953 F.2d 909,

915-16 & n.7 (5th Cir.), *cert. denied,* 506 U.S. 832 (1992). "Only disputes over facts that might affect the outcome of the suit under the governing laws will properly preclude the entry of summary judgment." *Anderson,* 477 U.S. at 248. Disputed fact issues which are "irrelevant and unnecessary" will not be considered by a court in ruling on a summary judgment motion. *Id*. If the nonmoving party fails to make a showing sufficient to establish the existence of an element essential to its case and on which it will bear the burden of proof at trial, summary judgment must be granted. *Celotex*, 477 U.S. at 322-23.

B. Parties' Contentions

Defendants move to dismiss all of Plaintiffs' claims against them. They contend that Plaintiffs cannot establish as a matter of law that Motrin caused Decedent's death because they lack scientifically-reliable evidence of causation. They also argue that Plaintiffs' failure to warn claims are barred by Texas's statutory presumption that FDA-approved warnings are adequate. They further argue that Plaintiffs' claims are preempted by federal law. Next, they contend that Plaintiffs' defective design claim is not cognizable under Texas law. They argue that Plaintiffs' DTPA claim fails because that act exempts personal injury and wrongful death claims. They contend that Sandy Lofton's claims and Plaintiffs' survival claims are time-barred. Finally, they argue that there is no evidence to support Plaintiffs' claims for punitive and treble damages. Plaintiffs contend that they have sufficient evidence for each of the grounds raised by Defendants and argue that the motion should be denied.

The court abated this case for one year until the Supreme Court decided the case of *Wyeth v. Levine*, 128 S. Ct. 1118 (2008). After that case was decided and the court reopened the case, it directed the parties to submit supplemental briefs regarding the effect of *Wyeth* on this case. The

court will consider the parties' supplemental arguments when it considers the preemption arguments.[1]

Defendants also filed objections to Plaintiffs' summary judgment evidence. These objections overlap Defendants' contentions raised in their *Daubert* motion. To the extent the magistrate judge's order ruled on these objections, the court **overrules as moot** Defendants' objections.

C. Analysis

1. Causation

Defendants contend that Plaintiffs cannot establish general causation because there is no admissible evidence to show a link between ibuprofen and SJS/TEN. In support of this argument, Defendants incorporate their briefing on the motion to exclude Plaintiffs' expert witnesses. Defendants point to the 2008 Mockenhaupt study,[2] which found a relative risk of 0.9 with a 95% confidence interval from 0.3 to 2.6, and contend that this is the most reliable study. They argue that the 2008 Mockenhaupt study establishes that there is no link between ibuprofen and SJS/TEN.

Plaintiffs respond that there are links between the skin disorders at issue and drugs. They submit affidavits of their experts, relying upon adverse event reports and epidemiological studies. They contend that the 2008 Mockenhaupt study is suspect and that causation is a fact question that should be submitted to the jury.

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[1]Plaintiffs' supplemental brief addresses preemption with respect to the *Wyeth* decision and their argument regarding section 82.007 of the Texas Civil Practice and Remedies Code. They have also filed a supplemental appendix containing deposition testimony and a study not previously submitted and not referred to in their supplemental brief. The court only sought supplementation regarding the effect of *Wyeth*. Accordingly, it does not consider Plaintiffs' supplemental evidence.

[2]There are two studies at issue in this case that were published by Maja Mockenhaupt. The first, *The Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis Associated with Nonsteroidal Anti-Inflammatory Drugs: a MultiNational Perspective*, was published in 2003 (hereinafter, the "2003 Mockenhaupt study"). The second, *Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis: Assessment of Medication Risks with Emphasis on Recently Marketed Drugs. The EuroSCAR-Study*, was published in 2008 (the "2008 Mockenhaupt study").

Defendants contend that there are three seminal epidemiological studies regarding the relationship between ibuprofen and SJS/TEN, and these studies analyze data from the Severe Cutaneous Adverse Reactions study (the "SCAR study") and the European Ongoing Case-Control Surveillance of Severe Cutaneous Adverse Reactions (the "EuroSCAR study"). According to Defendants, the first study, the Roujeau study,[3] did not reach statistical significance and therefore does not meet the *Havner* standards. Defendants state that the second study, the 2003 Mockenhaupt study, found a relative risk of 5.3 for ibuprofen. Finally, the third study, the 2008 Mockenhaupt study, concluded that the risk from ibuprofen was extraordinarily low and that it was probably not associated with skin reactions such as SJS/TEN. Defendants argue that the only study showing a link between ibuprofen and SJS/TEN that meets the *Havner* standards, the 2003 Mockenhaupt study, is no longer valid in light of the 2008 Mockenhaupt study.

Defendants argue that most of Plaintiffs' experts ignore the 2008 Mockenhaupt study in their reports. They also contend that Plaintiffs' expert reports are flawed because they rely heavily upon case reports. Defendants assert that Plaintiffs' experts fail to separate classes of NSAIDs and that many of their conclusions have not been published or peer-reviewed.

Plaintiffs respond that their experts rely on epidemiological studies, clinical studies, and adverse event reports, and that since 1978, these sources have shown an association between ibuprofen and SJS/TEN. They also argue that their experts are critical of the 2008 Mockenhaupt study, questioning the assumptions used in the 2008 study as opposed to the 2003 study and the validity of the study based upon the mixture of countries and patients and the differences in the number of patients and controls between the two studies.

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[3]The Roujeau study refers to the 1995 study, *Medication Use and the Risk of Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis.*

Many of the arguments raised by Defendants were rejected by the magistrate judge because they go to the weight, not the admissibility, of the evidence. The court has accepted the magistrate judge's rulings and so simply must determine whether, under *Havner*, Plaintiffs' expert testimony is not legally sufficient to establish causation. The court determines that the 2008 Mockenhaupt study is not determinative of this question. Under *Havner*, the 2003 Mockenhaupt study is admissible; it meets the three criteria set forth in that opinion. The court does not read *Havner* to require rejection of an earlier study that meets its requirements simply because a later study contradicts it. The differences between the 2003 Mockenhaupt study and the 2008 Mockenhaupt study raise a fact issue with respect to general causation, and the parties will have the ability to question their experts as to the differences between the two studies. Because both studies meet the *Havner* criteria, the ultimate resolution of which study is to be believed is a fact question for the jury. Accordingly, the court determines that there is a genuine issue of material fact with respect to general causation.

2. Adequacy of the Motrin Label

Next, Defendants argue that the Motrin warning label, which was approved by the FDA, is presumptively adequate pursuant to section 82.007 of the Texas Civil Practice and Remedies Code. Next, they anticipate Plaintiffs' argument that a fraud-on-the-FDA exception applies and argue that this exception is preempted by federal law and that it fails in light of the FDA's conclusion that there is no evidence that Defendants withheld safety information. Plaintiffs respond that section 87.002 is not a cause of action and therefore there is no issue of preemption and that their evidence rebuts the statutory presumption.

Section 82.007(a) of the Texas Civil Practice and Remedies Code provides for a rebuttable presumption in certain products liability cases:

> In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if . . . the warnings or information that accompanied the product in its distribution were those approved by the [FDA] for a product approved under the Federal Food, Drug, and Cosmetic Act . . . or Public Health Service Act . . . .

Tex. Civ. Prac. & Rem. Code § 82.007(a)(1). This presumption may be rebutted by a claimant if he establishes that "the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the [FDA] required information that was material and relevant to the performance of the product and was causally related to the claimant's injury . . . ." *Id*. at § 82.007(b)(1).

a. Statutory Presumption

Defendants contend that they are entitled to the statutory presumption because the 2000 Motrin warning label complied with FDA requirements, including an October 21, 1998 rule requiring changes to an alcohol warning and a September 15, 1998 requirement directing the wording of the allergy portion of the label. Although the FDA later ordered that over-the-counter ibuprofen include additional allergy warnings relating to skin reddening, rash, and blisters, this requirement was not instituted until 2005, and Defendants complied with it at that time. The court determines that Defendants have made an initial showing that they are entitled to the statutory presumption in section 82.007. The court must now determine whether the fraud-on-the-FDA exception applies.

b. Fraud-on-the-FDA Exception

Defendants argue that the fraud-on-the-FDA exception to the statutory presumption does not apply in this case. They contend that this exception is preempted to the extent that anyone other than the FDA is asked to determine that material was withheld from the FDA. Defendants contend that the FDA has explicitly rejected the argument that they withheld information from it regarding the labeling of Motrin. In response to a Citizen's Petition submitted to the FDA seeking additional warnings about SJS/TEN on ibuprofen products, the agency stated:

> You state that manufacturers of ibuprofen drug products have withheld safety information regarding the risks of SJS and TEN associated with ibuprofen products and request FDA to conduct an investigation accordingly. You state that "McNeil and Wyeth have failed to provide the FDA full information regarding the safety issues surrounding serious skin reactions, including SJS/TEN that were not presented in their applications for their OTC pediatric formulations." However, you provide no evidence to support this allegation. In addition, we have no evidence that there is additional undisclosed safety information that was withheld by ibuprofen manufacturers. If you have any information to support this allegation, please provide it to us.

Defs.' App. 407 (citation omitted). Plaintiffs' expert admits that he has not provided information to the FDA because such information is subject to a protective order in another case. Defendants contend that no evidence of withholding information or making misrepresentations to the FDA has ever been provided. Even if the court were to consider the exception, Defendants argue that there is no evidence that they withheld information relating to Motrin from the FDA.

Defendants' preemption argument relies heavily upon *Ledbetter v. Merck & Co.*, 2007 WL 1181991 (Tex. Dist. – Harris Co. Apr. 19, 2007), an unpublished trial decision of a Texas state court

that is unavailable to the court[4] and that was not included in Defendants' summary judgment materials. *Ledbetter* apparently relies heavily upon the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), which held:

> [S]tate-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, federal law. The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law.

Id. at 348 (footnote omitted). Defendants do cite cases from other jurisdictions in which exceptions similar to those set forth in section 82.007(b) have been held to be preempted by *Buckman*. For example, the Sixth Circuit found:

> The Michigan legislature has provided a general immunity for drug manufacturers with a specific exception for circumstances involving, *inter alia*, fraud on the FDA rather than a specific cause of action for fraud on the FDA. This difference, however, is immaterial in light of *Buckman*. As the district court properly found, "*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims."

Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961, 965-66 (6th Cir. 2004) (footnote and citation omitted); *accord Zammit v. Shire US, Inc.*, 415 F. Supp. 2d 760, 768-69 (E.D. Mich. 2006); *Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166, 1171-75 (D. Ariz. 2005); *Grange v. Mylan Labs., Inc.*, 2008 WL 4813311, *7 (D. Utah Oct. 31, 2008); *In re Aredia and Zometa Prods. Liab. Litig.*, 2007 WL 649266, *8-9 (M.D. Tenn. Feb. 27, 2007), *aff'd* 2009 WL 4072074 (6th Cir. Nov. 24, 2009); *Henderson v. Merck & Co., Inc.*, 2005 WL 2600220, *11 (E.D. Pa. Oct. 11, 2005); *Duronio v.*

[4]Although a Westlaw citation has been provided by Defendants, the court's Westlaw subscription does not permit viewing this decision, and the case is not available on Lexis.

Merck & Co., Inc., 2006 WL 1628516, *5 (Mich. App. June 13, 2006). On the other hand, the Second Circuit explicitly rejected the result in *Garcia*. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 98 (2d Cir. 2006), *aff'd*, 552 U.S. 440 (2008).[5]

It appears that only two district courts in this circuit have considered this issue. A district court in the Eastern District of Texas considered both *Garcia* and *Desiano* and held, without adopting either view, that it would consider whether the plaintiff had set forth evidence to rebut the presumption:

> [T]he Court believes that the language of section 82.007(a) creates nothing more than a presumption which the Defendant is free to raise. It does not create a cause of action where none existed before. If Plaintiff comes forward with evidence that the FDA was somehow misled, Plaintiff has merely rebutted a presumption that the manufacturer is not liable. The rebuttal evidence does not establish liability. . . . Therefore, the only question is whether Plaintiff has set forth some evidence to prevent Wyeth from obtaining judgment in its favor in light of the statute. . . . The Court declines to recommend summary judgment based on a presumption.

Ackermann v. Wyeth Pharms., 471 F. Supp. 2d 739, 749-50 (E.D. Tex. 2006) (Schenider, J.), *aff'd on other grounds*, 526 F.3d 203 (5th Cir. 2008). In this district, another district judge followed *Ackermann*: "[S]ection 82.007 does not create a cause of action for fraud on the FDA . . .; it merely creates a presumption that [defendant] may rely upon in its defense. Because discovery is not completed in this case, it would be inappropriate to state that Plaintiff has not rebutted [defendant's] statutory presumption." *Pustejovsky v. Wyeth, Inc.*, Civil Action No. 4:07-CV-0103-Y, Order Denying Motion for Sum. J. and Motion to Strike (Nov. 29, 2007), 2-3 (Means, J.).

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[5]*Desiano* was affirmed by an equally-divided Supreme Court without an opinion. 552 U.S. 440 (2008). The Court's decision is therefore not binding on this court. *Hertz v. Woodman*, 218 U.S. 205, 213-14 (1910) ("[A]n affirmance by an equally divided court is, as between the parties, a conclusive determination and adjudication of the matter adjudged; but the principles of law involved not having been agreed upon by a majority of the court sitting prevents the case from becoming an authority for the determination of other cases, either in this or in inferior courts.").

Unlike the other courts in this district, this court determines that the rationale in *Garcia* is persuasive and that extending the holding of *Buckman* to fraud-on-the-FDA exceptions is warranted. The court finds that the concerns in *Buckman* hold true not only where a plaintiff brings a fraud-on-the-FDA claim but also where it seeks to show an exception to the presumption here. To avoid any intrusion upon the FDA's right to police fraud itself, the court follows *Garcia* and finds that section 82.007(b)(1) is preempted in some circumstances, including as here, where Plaintiffs ask the court to reach the conclusion opposite of that reached by the FDA, that Defendants did not withhold information or mislead it. Accordingly, the court finds that Defendants are entitled to the rebuttable presumption of section 82.007(a).

Therefore, there is no genuine issue of material fact whether Defendants' Motrin label in 2000 was adequate, and Defendants are entitled to judgment as a matter of law on Plaintiffs' claims that are premised upon their failure to warn about the risk and symptoms of SJS/TEN. Accordingly, the court determines that Plaintiffs' claims for marketing defect, breach of warranty, and negligence should be **dismissed with prejudice**.

3. Preemption

Defendants contend that Plaintiffs' state law claims are preempted by the FDA's regulatory scheme.[6] They argue that the FDA has made clear its position that state law tort claims are preempted because they interfere with the agency's regulatory role and that courts should defer to the FDA. In support of their argument, Defendants cite *Colacicco v. Apotex Inc.*, 521 F.3d 253 (3d Cir. 2008), which was subsequently vacated and remanded in light of *Wyeth*. Plaintiffs argue that their claims are not preempted, that manufacturers are permitted to change their labels without FDA

[6]Defendants appear to assert this defense to all of Plaintiffs' claims; thus the court considers it, even though it has determined that Plaintiffs' failure to warn claims should be dismissed.

approval, that state law claims complement the FDA's role and purpose, that there is no conflict between their claims and the FDA's actions with respect to Motrin, and that *Colacicco* is distinguishable.

The court abated this case to wait for the decision in *Wyeth* and ordered supplemental briefing in light of that decision. Plaintiffs argue that *Wyeth* supports their contention that their claims are not preempted. Defendants contend that *Wyeth* creates an exception to the general rule that state claims are not preempted where there is clear evidence that the FDA has rejected or would reject the proposed labeling sought by Plaintiffs.

Wyeth involved state law failure-to-warn claims regarding the drug Phenergan. 129 S. Ct. at 1190-91. The FDA had approved the warnings on the Phenergan label when it was approved in 1955, and later when the manufacturer made changes to the drug's label. *Id*. at 1191. Wyeth argued that plaintiff Diana Levine's claims were preempted for two reasons:

> [F]irst, that it would have been impossible for it to comply with the state-law duty to modify Phenergan's labeling without violating federal law, and second, that recognition of Levine's state tort action creates an unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress because it substitutes a lay jury's decision about drug labeling for the expert judgment of the FDA.

Id. at 1193-94 (internal citations and quotations omitted). The Court rejected both arguments.

In addressing the first argument, the Court considered the FDA's regulations regarding drug labels. It noted that generally a manufacturer needed FDA approval to change a drug label. *Id*. at 1196. There is, however, a "changes being effected" ("CBE") regulation that allows a manufacturer to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use

of the drug product" upon filing a supplemental application with the FDA without waiting for FDA approval. *Id*. (citing 21 C.F.R. §§ 314.70(c)(6)(iii)(A), (C)). The Court emphasized that the statute and regulations have long contained "a central premise . . . that the manufacturer bears responsibility for the content of its label at all times." *Id*. at 1197-98. Taking this history into account, it determined that "absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements." *Id*. at 1198. It found that Wyeth had offered "no such evidence." *Id*.

The Court also rejected Wyeth's second argument that allowing Levine's state law claims would interfere with federal drug labeling regulations. It explicitly rejected Wyeth's argument that the FDA establishes "both a floor and a ceiling" for drug regulation. In reaching this decision, the Court considered the FDA's statement in the preamble to a 2006 regulation (the "FDA preamble"). *Id*. at 1200 (citing 71 Fed. Reg. 3922 (2006)). It determined that the FDA preamble "does not merit deference." *Id*. at 1201. It concluded:

> Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling. Congress has repeatedly declined to pre-empt state law, and the FDA's recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight. Although we recognize that some state-law claims might well frustrate the achievement of congressional objective, this is not such a case.

Id. at 1204.

In light of *Wyeth*, it is clear that most state law labeling claims are not preempted, but it must determine if there is a material question of fact whether "the FDA would not have approved a change" to Motrin's label. *Id*. at 1198. Defendants contend that Plaintiffs' claims fall within this

exception and are therefore preempted. Plaintiffs argue that *Wyeth* holds that their claims are not preempted, that the FDA ultimately made the changes to the Motrin label that they contend should have been made, and that had Defendants changed the label to include these warnings, Decedent would not have taken Motrin in 2000.

Defendants argue that the evidence establishes that even if requested, the FDA would not have approved a change to the Motrin label to warn of SJS/TEN. In support, they point to the affidavit of Dr. Anthony Temple, who states that the FDA refused the request in the Citizen's Petition to remove ibuprofen products from the marketplace or to mention SJS or TEN in the label. Defendants also argue that at the time the FDA was considering the Motrin label in place when Decedent took the drug, the prescription Motrin label explicitly mentioned a risk of SJS/TEN. They contend that the FDA made a risk-benefit decision to include a warning for the prescription drug but not for the over-the-counter version. Defendants also point to the FDA's 2006 decision in response to the Citizen's Petition and its conclusion that a specific reference to SJS/TEN was appropriate for physicians but not for laypersons.

In response to the Citizen's Petition, the FDA stated:

> We agree that the labeling for OTC NSAIDs, including all ibuprofen products, should be improved to warn consumers about the risks of severe skin reactions associated with OTC ibuprofen products. As a result, we have requested that manufacturers include under the *Allergy alert* subheading the symptoms associated specifically with SJS and TEN. We do not believe that it is useful to include the specific terms *SJS, TEN*, or *erythema multiforme, Stevens-Johnson syndrome,* and *toxic epidermal necrolysis* in the OTC label because most consumers are unfamiliar with these terms. In addition, effective OTC labeling communicates warning information in a manner that consumers can quickly and easily identify and understand. Consequently, we believe that a description of symptoms is more appropriate, Therefore, prominently displayed

> under the *Allergy alert* subheading in the Drug Facts Label, the labeling will include:
>
> - skin reddening
> - rash
> - blisters
>
> In addition, under the *Allergy alert* subheading, the labeling will state: "If an allergic reaction occurs, stop use and seek medical help right away." We believe that adding these symptoms to the *Allergy alert*, with advice to stop use and seek medical attention immediately, will alert and educate consumers to the nature of the allergic reactions associated with SJS and TEN.

Defs.' App. 409-10 (citations omitted) (italics in original).

The court is mindful that the Supreme Court noted that "impossibility pre-emption is a demanding defense." *Wyeth*, 129 S. Ct. at 1199. It also notes that Plaintiffs have not pleaded claims that Defendants failed in warning only about SJS and TEN. They contend that "there was no warning, or alternatively no adequate warning, that [Motrin's] consumption or ingestion could result in SJS or TEN or in any type of severe and/or life-threatening skin reaction." Compl. ¶ 4.3. They further plead: "Specifically, there was no warning about the early symptoms of SJS and TEN, including that if a rash or mucosal reaction developed, the drug should be stopped immediately and medical care sought." *Id*. at ¶ 4.4.

If Plaintiffs' claim were limited to a failure to specifically warn that SJS and TEN were possible side effects of Motrin, the court would agree with Defendants and conclude that this case falls within the limited exception because the evidence shows that the FDA would have rejected adding those specific medical conditions to the Motrin label. Plaintiffs' claims, however, are broader and include the failure to warn of the symptoms of SJS and TEN, symptoms that ultimately were added to the Motrin label at the FDA's direction. Accordingly, the court cannot determine,

as a matter of law, that the FDA would not have changed the label to add early symptoms and therefore that Plaintiffs' claims are preempted.

4. Defective Design

Next, Defendants argue that Plaintiffs' defective design claim is not recognized under Texas law. They contend that a manufacturer is not liable for injuries caused by a drug that was properly prepared and accompanied by warnings known or scientifically knowable at the time of distribution. They also argue that there is no scientifically-reliable basis to support the claim, as raised in Defendants' *Daubert* motion.

Plaintiffs respond that *Havner* recognizes a claim for defective design under Texas law. They further contend that the case law relied upon by Defendants includes a narrow exception that is not applicable to this case. They contend that they can show a safer alternative design for the drug in question and therefore summary judgment on this claim is unwarranted.

Defendants rely primarily upon *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591 (W.D. Tex. 2002), in support of their motion for summary judgment on this claim. In that case, the court relied upon comment k to section 402A of the Restatement (Second) of Torts relating to unavoidably unsafe products. *Id*. at 595. That comment states that an unavoidably unsafe product "properly prepared, and accompanied by proper directions and warnings, is not defective, nor is it unreasonably dangerous." *Id*. (citing Restatement (Second) of Torts § 402A cmt. k (1965)). The court noted that Texas courts have applied comment k to prescription drug claims and concluded that "under Texas law and comment k of the Restatement, Defendants can only be held strictly liable if the drug was not properly prepared or marketed or accompanied by proper warnings." *Id*. (citations omitted).

Plaintiffs argue that comment k does not apply in this case and that Defendants cannot contend that Motrin is safe and effective on the one hand and that it is an unreasonably dangerous product on the other hand. They also point to the affidavit of Dr. Tackett, who opines that the racemic ibuprofen found in Motrin is associated with SJS/TEN while dexibuprofen is not.

Defendants have cited no cases applying comment k to an over-the-counter drug; the cases cited all apply it only to prescription drugs. Comment k itself refers to drugs, "many of which . . . cannot be legally sold except to physicians, or under the prescription of a physician." Restatement (Second) of Torts § 402A cmt. k. The court will not take a leap not taken by Texas courts and apply this exception to an over-the-counter drug, even if at one time ibuprofen was a prescription drug. At the time Decedent took the drug it was not.

The court has also already determined that Dr. Tackett's opinions regarding the defective design theory are admissible. To the extent Defendants' experts disagree, this creates matters for the jury to resolve. Accordingly, the court determines that there are genuine issues of material fact with respect to Plaintiffs' defective design claim, and therefore summary judgment is not warranted on this claim.

5. DTPA Claims

Defendants move for summary judgment on Plaintiffs' DTPA claim, contending that these are claims for bodily injury and wrongful death that are not permitted under that statute. They cite section 17.49(e) of the Texas Business and Commerce Code, which provides that "[e]xcept as specifically provided by Subsections (b) and (h), section 17.50, nothing in this subchapter shall apply to a cause of action for bodily injury or death or for the infliction of mental anguish." They contend that Plaintiffs' claims do not fall within the exceptions set forth in the enumerated

subsections. They further argue that some Texas courts have held that DTPA claims do not survive a decedent's death.

Plaintiffs respond that the DTPA allows for breach of warranty claims, which they have alleged. They contend that they have experienced economic damages and mental anguish. They argue that if these claims are duplicative of their warning claims, the court should not dismiss their DTPA claims until evidence has been presented. They further argue that the DTPA does not preclude a breach of warranty claim even though personal injuries may be alleged. Plaintiffs do not specifically respond to Defendants' survivability argument.

The court determines that Defendants are correct and that Plaintiffs' claims fail because they did not survive the death of Decedent. The court notes that while the Texas Supreme Court has been silent on the issue of whether DTPA claims survive the death of the consumer, at least one court in this district has found that such claims do not survive. *Launius v. Allstate Ins. Co.*, 2007 WL 1135347, *5 (N.D. Tex. Apr. 17, 2007) (Boyle, J.).[7] In *Launius*, the court considered the split between intermediate Texas appellate courts as well as the Texas Supreme Court's decision in *PPG Industries, Inc. v. JMB/Houston Centers Partners Ltd.*, 146 S.W.3d 79 (Tex. 2004). This court finds that this decision is well-reasoned and adopts its conclusion:

> [B]ased on an extension of the Texas Supreme Court's reasoning in *PPG Industries*, and on [several San Antonio Court of Appeal decisions], this Court believes that the Texas Supreme Court, if confronted with the issues in this case, would find that a consumer's cause of action under the DTPA does not survive the death of the consumer and cannot be brought by a representative of the consumer's estate.

[7]Defendants also cite *Kirby v. B.I. Inc.*, Civil Action No. 4:98-CV-1136-Y (N.D. Tex. Sept. 26, 2003), in support of this argument. This decision is not available on Westlaw and has been permanently sealed by the court.

Launius, 2007 WL 1135347 at *5. Accordingly, because the court concludes that the DTPA claim did not survive the death of Decedent, the court determines that this claim should be **dismissed with prejudice**.

6. Limitations

Defendants next argue that all Plaintiffs' claims are barred by limitations except for the individual wrongful death claims brought by each of Decedent's three children, Christopher Tyler Lofton, Tegan Nicole Lofton, and Lauren Lofton. They contend that the wrongful death claim brought by Decedent's wife, Sandy Lofton, is time-barred. They further contend that Plaintiffs' survival claims are barred because they were not filed within three years of Decedent's death.

Plaintiffs respond that the discovery rule does not apply to Sandy Lofton and Decedent's estate claims because they have pleaded fraudulent concealment. They contend that Sandy Lofton did not know of a connection between Motrin and SJS/TEN until the 2005 Citizen's Petition and that she did not understand the autopsy report when she received it. They also state that although she contacted an attorney after her husband's death, she was told that there was no medical malpractice.

The statute of limitations for a wrongful death action is two years. Tex. Civ. Prac. & Rem. Code § 16.003(b). "The cause of action accrues on the death of the injured person." *Id*. With respect to survival claims, "[t]he death of a person against whom or in whose favor there may be a cause of action suspends the running of an applicable statute of limitations for 12 months after the death." *Id*. at § 16.062. For the minor children, the time that they were younger than 18 years of age is not included in the limitations period. *Id*. at § 16.001.

The court determines that Plaintiffs' wrongful concealment contentions are without merit. Decedent died on June 3, 2000. Sandy Lofton admits that she received a copy of the autopsy report

no later than June 2001. That report states: "In summary, [Decedent] died as a result of drug (acetaminophen and/or ibuprofen) induced toxic epidermal necrolysis complicated by sepsis." Defs.' App. 54. Plaintiffs did not bring file this civil action until July, 1, 2005, more than four years after the latest date that she was on notice of a possible link between ibuprofen and her husband's death. The court has also held that the FDA determined that Defendants did not withhold or misrepresent information to the agency with respect to the Motrin label. Accordingly, the court determines that Sandy Lofton's wrongful death claim is barred by the statute of limitations. Similarly, the court determines that any survival claim brought by Sandy Lofton is also barred because it was not filed within three years of Decedent's death.

The parties do not dispute that Decedent's children's wrongful death claims are timely.[8] The only remaining dispute is whether the children can assert survival claims that were tolled because of their minority. Defendants acknowledge cases that have held that minor children's survival claims are tolled but argue that these decisions are incorrect as a matter of law.

In *County of Dallas v. Sempe,* 151 S.W.3d 291, 297 (Tex. App. – Dallas 2004), the court held that the limitations period for a minor's survival action is tolled while the child is a minor. Citing sections 16.001(b) and 16.003, that court held that the minor children's action "was tolled during the period of their minority." *Id*. The court will follow *Sempe* and holds that the minor children's survival claims are not barred by the statute of limitations.

Accordingly, the court determines that summary judgment on Sandy Lofton's wrongful death and survival claims is warranted because they are barred by the statute of limitations. The court will

[8]At the time Plaintiffs filed their petition in state court, Tegan Lofton was 14, Lauren Lofton was 17, and Christopher Tyler Lofton was 19. Pls.' Orig. Pet. 11. Defendants concede that their wrongful death claims are not barred by limitations.

dismiss Sandy Lofton's claims **with prejudice**. The children's wrongful death and survival claims, however, are timely.

7. Damages

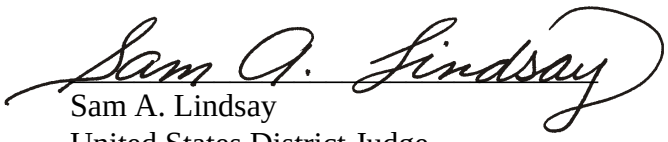
Finally, Defendants move for summary judgment on Plaintiffs' claims for punitive and treble damages. They argue that Plaintiffs cannot show that they are entitled to damages for fraud, malice, or gross negligence, pursuant to the DTPA, or for their defective design claim. In response, Plaintiffs list four bases for their contention that Defendants were grossly negligent.

The court has found that Plaintiffs' DTPA and failure to warn claims should be dismissed with prejudice, but they are entitled to proceed on their defective design claim. To the extent some of Plaintiffs' claims have survived the motion for summary judgment, the court defers ruling on this ground until trial.

IV. Conclusion

For the reasons stated herein, the court **overrules** Defendants' Objections to Magistrate Judge's Order; **overrules as moot** Defendants' Objections to Plaintiffs' Summary Judgment Evidence; and **grants in part** and **denies in part** Defendants' Motion for Summary Judgment. The court **dismisses with prejudice** Sandy Lofton's wrongful death and survival claims, Plaintiffs' marketing defect claim, Plaintiffs' breach of express warranty claim, Plaintiffs' negligence claim, and Plaintiffs' DTPA claim. Remaining for trial are the wrongful death and survival claims of Christopher Tyler Lofton, Lauren Lofton, and Tegan Lofton for defective design and breach of implied warranty.

It is so ordered this 27th day of January, 2010.



Sam A. Lindsay
United States District Judge